

**UNITED STATES PATENT APPLICATION**  
**FOR**  
**MALE CLEAN INTERMITTENT CATHETER SYSTEM**

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# **MALE CLEAN INTERMITTENT CATHETER SYSTEM**

## **PRIORITY CLAIM**

5 This application is a continuation of and claims the benefit of and priority to U.S. Patent Application 09/879,321, filed June 12, 2001 which claims the benefit of provisional application Serial No. 60/211,152, filed June 13, 2000.

## **CROSS-REFERENCE TO RELATED APPLICATIONS**

10 This application is related to the following commonly-owned co-pending patent applications: "METHOD FOR DETERMINING THE CONTENT OF A SELF-CARE KIT," Serial No. 09/709,917, Attorney Docket No. 0110430-020; "PATIENT DISCHARGE SYSTEM AND METHOD FOR SELF-CARE OF A POST-SURGERY DRAIN," Serial No. 09/779,796, Attorney Docket No. 0110430-022, now U.S. Patent No. 6,579,271; and "FEMALE CLEAN  
15 INTERMITTENT CATHETER SYSTEM," Serial No. 09/879,230, Attorney Docket No. 0110430-026.

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## **25 DESCRIPTION**

The present invention relates in general to a system and method for using a male catheter and in particular to a system and method for clean intermittent male catheterization by a user or health care provider.

## **30 BACKGROUND OF THE INVENTION**

It is estimated that urinary catheters are placed in millions of men each year in the United States alone, either due to some illness, infection or

malfunction or as part of some medical procedure. Care must be taken to clean the catheter site to reduce the risk of nosocomial infection (i.e., an infection that arises due to a procedure for treating a disorder and unrelated to the disorder itself, also referred to as a "hospital infection").

5           The most common nosocomial infections are related to or arise from indwelling urinary bladder catheters (i.e., catheters that remain in the urinary tract for a relatively long length of time). The risk of such catheter-related nosocomial infections can be reduced using strict aseptic techniques (i.e., using gloves, disinfectants, antibacterial soaps, etc.) when handling the  
10 catheter. Moreover, the risk of infection can further be reduced by only using a catheter intermittently rather leaving the catheter in place for any length of time. Intermittent use of the catheter in conjunction with clean techniques helps to reduce the risk of catheter-related nosocomial infections and is, moreover, a far more attractive alternative for bladder evacuation to most  
15 patients who are candidates for the procedure.

          Using a urinary bladder catheter under aseptic conditions in a hospital is routine. However, current medical practice emphasizes getting the patient ambulatory (and out of the hospital) as soon as possible. Consequently, catheterizations or catheter insertions are performed at home by  
20 nonprofessionals. These nonprofessionals must be taught clean techniques. However, no known comprehensive devices, apparatus or methods exists for teaching clean techniques or for facilitating such home catheter use for men.

## SUMMARY OF INVENTION

25           The present invention provides a method and system for intermittent catheterization by the patient himself, the patient's caregiver, or a health care provider. The present invention contains apparatus for facilitating at least one catheterization and comprises: (I) at least one male catheter; (II) antibacterial soap; (III) lubricant; (IV) step-by step instructions; and (V) a container, where  
30 the above named items are positioned inside the container. It should be appreciated that the present invention may only be used on the order of a physician.

Preferred embodiments of the system contain sufficient apparatus for one month of catheter insertions (approximately 3 to 4 times a day), the antibacterial soap is in liquid form, the lubricant is in gel form, the step-by-step instructions are written in English and Spanish, although other languages (e.g.,  
5 Polish, French and German for example) are contemplated. One preferred embodiment of the system includes a contents map identifying the contents and the positions of the contents, along with zipper bags, a fanny pack and a protective underpad.

In a more preferred embodiment of the system, the system contains  
10 apparatus for at least one month of catheterizations as provided previously and comprises: (I) 4 male intermittent catheters; (II) 35 disposable wipes; (III) 1 protective underpad; (IV) antibacterial liquid soap; (V) 1 tube of lubricant; (VI) step-by-step instructions; (VII) clinician step-by-step instructions or self-care documentation; and (VIII) a box, wherein the above-named items are  
15 positioned inside the box.

The method for intermittent male catheterization comprises evacuating the bladder using the apparatus of the present invention in accordance with the detailed step-by-step instructions provided in the system. In a preferred embodiment, the method which is discussed in further detail below generally  
20 includes: (I) preparing for intermittent male catheterization; (II) preparing the male catheter; (III) inserting the male catheter; (IV) draining the bladder; (V) recording and disposing of the drainage; and (VI) cleaning and storing the apparatus of the present invention.

The present invention further includes a patient education system for  
25 educating users in performing intermittent male catheterization. Specifically, the system includes a system and a set of black and white step-by-step instructions without illustrations (referred to herein as self-care documentation). An instructor (i.e., a doctor, nurse, clinician or other medical professional) uses the self-care documentation to educate the user in  
30 performing an intermittent male catheterization, preferably using the system of the present invention. The medical professional then keeps the self-care

documentation documenting that the user was educated in performing the male catheterization.

It is therefore an object of the present invention to provide a system and method for intermittent male catheterization.

5        It is a further object of the present invention to provide detailed instructions for intermittent male catheterization using the contents of a self-care system.

10        An additional object of the present invention is to provide self-care documentation to be used by a medical professional in instructing users in the use of the self-care system.

Yet an additional object of the present invention is to provide a patient education system for educating users in performing intermittent male catheterization using the system.

15        Other objects, features and advantages of the invention will become apparent from the following detailed disclosure, taken in conjunction with the accompanying sheets of drawings, wherein like numerals refer to like parts, components and processes.

#### BRIEF DESCRIPTION OF THE DRAWINGS

20        Fig. 1 is a perspective view of the system of the present invention;  
Fig. 1A is a top plan view of a contents map of the present invention;  
Figs. 2A and 2B are top plan views of the step-by-step instructions in English of the system of the present invention;  
Figs. 3A and 3B are top plan views of the step-by-step instructions in  
25        Spanish of the system of the present invention;  
Fig. 4 is a top plan view of the self-care documentation in English used by a medical professional for documenting that the users are instructed in the use of the system of the present invention; and  
Fig. 5 is a top plan view of the urine record card.

## DETAILED DESCRIPTION OF THE INVENTION

It should be appreciated that the figures include one or more of the following trademarks which may be used by the assignee of this application:

5 (a) CAREGUIDE; and (b) CAREGUIDE and DESIGN. It should be appreciated that these trademarks are not part of the present invention.

The present invention is for a system 10 and method for intermittent catheterization of a patient. The user may be the patient himself, the patient's caregiver, an in-home care provider or a healthcare provider which, for brevity,  
10 are referred to herein as the "user." The system 10 provides apparatus needed for in-home catheterization.

In general, the intermittent catheterization system 10 contains at least: (I) infection prevention devices (gloves, disposable wipes, zipper bags, alcohol gel (i.e., a waterless cleaner), soap, and protective underpads); (II) insertion  
15 devices (catheter and lubricant); (III) recording devices (urine record card and collection basin); and (IV) information devices (step-by-step instructions, contents map and self-care documentation) among other items.

More specifically, as illustrated by Figs. 1 and 1A, the intermittent catheterization system 10 of the present invention comprises: (I) gloves 12;  
20 (II) a collection basin 14; (III) disposable wipes 16; (IV) protective underpad 18; (V) antibacterial soap 24; (VI) lubricating gel 20; (VII) male intermittent catheter 22; (VIII) clean and used zipper bags 26 and 28 respectively; (IX) self-care documentation 44 (not shown in Figs. 1 and 1A); (X) step-by-step instructions 34 (not shown in Figs. 1 and 1A); and (XI) a container or box 40. It is  
25 contemplated that the system 10 may also include a contents map 42 which identifies the contents of the container 40 and their position, and one or more waste bags.

In one preferred embodiment, the container 40 contains gloves 12, a plastic collection basin 14 with graduated markings, disposable wipes 16,  
30 protective underpads 18, single doses of lubricating gel 20a, male 14 catheters 22, antibacterial liquid soap 24, clean catheter zipper bags 26, a used catheter zipper bag 28, alcohol gel 30, a urine record card 32, a lubricating gel tube 20, a fanny pack 38, a travel wipe pack 46, illustrated step-

by-step instructions documentation 34 as revealed by Figs. 2A and 2B, and 3A and 3B, and self-care documentation 44). It should be appreciated that system 10 could be provided to the patient in a box, tray, bag, container or any other suitable content holder device 40. A box is preferred because it is strong enough to protect the contents of the system 10 and yet is suitable for shipping and storing. If a bag, tray, container or other content holding devices are used, a contents map 42 may or may not be included with system 10.

In one preferred embodiment, a urologist, clinician or other medical professional provides system 10 to the user, although it is contemplated that the user could obtain system 10 through other means provided that a medical professional has ordered the system for the patient. System 10 includes extremely detailed and specific step-by-step instructions 34 as illustrated in Figs. 2A and 2B that the user uses with the intermittent catheterization system 10 (specific step-by-step instructions in Spanish are illustrated in Figs. 3A and 3B). System 10 also includes the self-care documentation 44 the medical professional uses to document or record the instructions provided to the user in the use of the intermittent male catheterization system 10 as illustrated in Fig. 4. A difference between the two sets of instructions is that the instructions in Fig. 4 are black and white and include acknowledgment sections 45A and 45B while the instructions in Figs. 2A and 2B are illustrated in color (not shown) for ease of use by the patient. It is also contemplated that system 10 could include an instructional video, training the user in the use of the system 10.

In one preferred embodiment, system 10 includes sufficient apparatus for one month of male catheter insertions, the antibacterial soap 24 is in a liquid form, the lubricant 20 is provided in a gel or ointment form, and the step-by-step instructions 34, and the contents map 42 (if included) are written in English. While not necessary, one preferred embodiment also includes one or more gloves 12, disposable wipes 16 and a protective underpad 18. It should be appreciated that a user could order a refill of the disposable apparatus of the present invention using an order form provided with the apparatus of the present invention.

In a more preferred embodiment of the system, system 10 includes apparatus for at least one month of catheterizations and comprises: (I) 10 gloves 12; (II) 1 collection basin 14; (III) 35 disposable wipes 16; (IV) 3 protective underpads 18; (V) 10 single tubes of lubricating gel 20; (VI) 4 male  
5 intermittent catheters 22; (VII) antibacterial liquid soap 24; (VIII) 4 clean catheter zipper bags 26; (IX) 1 used catheter zipper bag 28; (X) 4 oz of alcohol gel 30; (XI) 1 urine record card 32; (XII) 1 lubricating gel tube 20; (XIII) a fanny pack 38; (XIV) 1 pack of travel wipes 46; (XV) self-care documentation 44; (XVI) detailed step-by-step instructions 34; (XVII) a contents map 42; and  
10 (XVIII) container or box 40 wherein the above-named items are positioned inside the box 40.

The system 10 includes apparatus necessary for intermittent male catheterization in accordance with the method. The system 10 organizes the apparatus in an easy-to-find format. The step-by-step instructions 34 indicate  
15 when an item is first required during the method and should be removed from the container 40 (preferably using red text to indicate when an item is first required). Using the step-by-step instructions 34 and the contents map 42, users can easily identify when each item is required in the method and readily find it in the container 40. It should be appreciated that the items and step-by-  
20 step instructions 34 could be color coded and/or use icons making identifying each item even easier. For example, the antibacterial soap 24 could be identified by a bubbles icon and blue coloring corresponding to a bubbles icon and blue color in the step-by-step instructions 34.

The method of the present invention generally comprises using the  
25 system 10 in accordance with the detailed step-by step instructions 34. In a preferred embodiment, the method generally includes: (I) preparing for intermittent male catheterization; (II) preparing the male catheter; (III) inserting the male catheter; (IV) draining the bladder; (V) recording and disposing of the drainage; and (VI) removing the male catheter and cleaning and storing the  
30 apparatus.



### Preparing for Intermittent Male Catheterization (Step I)

The first step of the method of the present invention, is illustrated by Figs. 2A and 2B and includes preparing and caring for the male catheterization site. Preparing and caring for the catheterization site includes: (I) obtaining a  
5 clean, fresh towel; (II) washing using the antibacterial liquid soap 24 and warm water, and using the clean towel for drying; (III) finding a safe, flat, uncluttered, solid surface; (IV) putting on the gloves 12 only if the catheterization is being performed by a user other than the patient which includes: (a) taking a pair of gloves 12 out of the box 40; and (b) putting them on; (V) preparing the surface  
10 which includes: (a) obtaining two clean, fresh paper towels; (b) opening the two paper towels; (c) placing the opened paper towels on the surface; (d) taking a protective underpad 18 out of the box 40; (e) opening the protective underpad 18; and (f) placing the opened protective underpad 18 under the patient's buttocks and near the opened paper towels; (VI) cleaning  
15 the catheter site which includes: (a) taking a paper wash cloth or disposable wipe 16 out of the box 40; (b) taking the container of antibacterial soap 24; (c) squeezing out approximately one or two drops of soap 24 onto the center of the wipe 16; and (d) gently washing the site using the wipe 16, the soap 24 and warm water; (VII) rinsing clean the wipe 16 which includes: (a) rinsing the  
20 wipe 16; (b) squeezing out the excess water, leaving the wipe 16 damp; and (c) placing the damp wipe 16 on one corner of the paper towel; and (VIII) washing using the antibacterial soap 24 as described previously. It should be appreciated that step (VIII) can be skipped if the user is wearing gloves 12. It is also contemplated that step I could include: (IX) preparing a  
25 waste bag comprising: (a) obtaining a waste bag; (b) opening the waste bag; and (c) setting the waste bag on the flat surface.

### Preparing The Male Catheter (Step II)

The second step of the method as illustrated includes inserting the  
30 catheter 22 into the penis. Inserting the catheter 22 includes: (I) taking a catheter 22 out of the box 40; (II) laying the catheter 22 on the paper towels; (III) take a collection basin 14 out of the box 40 and placing it near the paper

towels; (IV) applying the lubricating gel 20 which includes: (a) taking the lubricating gel tube 20 out the box 40; (b) flipping open the cap of the lubricating gel tube 20; (c) squeezing 3 inches of lubricating gel 20 onto the catheter 22 starting at the tip, being careful not to touch the catheter 22 with the tube 20; (d) rolling the catheter 22 in the lubricating gel 20 so that all sides are covered; (e) lifting the catheter 22 away from the paper towel and laying the wide end of the catheter 22 in the collection basin 14; and (f) moving the basin 14 close to the user so that the wide end of the catheter 22 is not accidentally pulled out of the basin 14.

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#### Inserting the Male Catheter (Step III)

The third step of the present invention comprises inserting the catheter 22 into the penis. Inserting the catheter 22 comprises: (I) sitting on the underpad 18; (II) holding the penis straight out with one hand; (III) pulling the penis away from the body keeping the urinary tract straight; (IV) inserting the catheter 22 until a bit (i.e., at least a drop) of urine appears; and (V) slowly pushing the catheter 22 in one inch more.

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#### Draining the Bladder (Step IV)

The fourth step of the method comprises draining the site (i.e., the bladder) forming a drainage. Draining the bladder using the catheter 22 comprises: (I) placing or holding the basin 14 in proximity to the tip of the catheter 22; (II) lowering the angle of the penis; (III) holding the catheter 22 in place and emptying the bladder into the basin 14; and (IV) slowly pulling the catheter 22 out when the bladder is empty (i.e., the urine stops).

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#### Recording and Disposing of the Drainage (Step V)

The next step of the method includes recording and disposing of the drainage. This step includes: (I) recording the amount of the drainage, including: (a) measuring the drainage level using the markings on the basin 14; (b) writing this amount on the urine record card 32 illustrated in Fig. 5; (c) noticing the color and smell of the drainage; and (d) recording the color and

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smell on the urine record card 32; and (II) disposing of the drainage, preferably emptying the basin 32 in a toilet.

#### Cleaning and Storing the Apparatus (Step VI)

5           The next step includes completing the intermittent catheterization in accordance with the method. Completing the catheterization includes: (I) cleaning the used catheter, which includes: (a) washing the used catheter 22 with the antibacterial soap 24 and warm water; (b) holding the catheter 22 under running tap water, rinsing it well inside and out; (c) shaking the catheter  
10 22 several times to remove any excess water; and (d) placing the catheter 22 on a clean, fresh paper towel to air dry; (II) removing any jelly left on the catheterization site using the damp wipe 16 (See Step I above); (III) cleaning the basin 14, which includes: (a) washing the basin 14 using antibacterial soap 24 and warm water; (b) rinsing the basin with warm water; and (c) placing the  
15 basin 14 on clean, fresh paper towel to air dry; (IV) closing the cap on the lubricating gel tube 20; (V) placing all the apparatus back in the box 40; (VI) placing the dry catheter 22 inside a clean catheter zipper bag 26, zipping it closed; (VII) placing the clean catheter zipper bag 26 in the box 40; (VIII) placing the dry basin 14 in the box 40; (IX) placing the underpad 18 in the  
20 box 40; and (X) disposing of the wipe 16 and the paper towels, preferably using the waste bags.

          It should be anticipated that the patient is not bed bound, but able and willing to get around. One preferred embodiment of the present invention includes a fanny pack 38 that enables users to travel. As illustrated in Figs. 2A  
25 and 2B, method provides that, for every four hours of travel, the fanny pack 38 should include: (I) one clean catheter 22 in a clean catheter zipper bag 26; (II) one packet of lubricating gel 20a; and (III) two clean paper towels. The fanny pack 38 should also include the pack of pre-wet travel wipes 46 and the used catheter zipper bag 28.

30           When catheterization is required, the user should find a place (preferably a bathroom) and follow Steps I-VI above, using clean paper towels for a clean work surface. After removing the catheter 22 in Step V, rinse it off if possible and store it in the used catheter zipper bag 28, placing the bag 28 in

the fanny pack 38. Wash as described previously in Step I. The used catheters may be cleaned completely upon returning home.

5 The present invention includes teaching or instructing users in the use of system 10. System 10 includes a set of extremely detailed instructions 34 and self-care documentation 44, as illustrated in Fig. 4. The self-care documentation is used by the medical care professional to instruct the users and for medical records.

10 Federal, state and local regulatory agencies require that the medical professional maintain complete records, including records to training provided to individuals. The medical care professional uses the self-care documentation 44 providing the instruction to the patient or user on the use the method and system 10 as illustrated in Fig. 4. The self care documentation enables the medical care professional to ensure that the training is complete, providing a signature box or acknowledgment areas 45A and 45B for the user to indicate that they received and understand the instructions. This documentation 44 is maintained by the clinician or a medical provider as part of the clinical record, where they may be used for accreditation and/or legal purposes.

20 The present invention further contemplates a patient education system for educating users in performing intermittent male catheterization. The system includes the system 10 and the self-care documentation 44. The present invention is only used on the order of a physician. An instructor (i.e., a doctor, nurse, clinician, other medical profession, or any individual trained to educate users in performing male catheterization) uses the self-care documentation 44 to train users to perform a male catheterization, preferably using the system 10. The instructor takes the user through the process of performing a male catheterization, and may even demonstrate specific procedures using specific items in the system 10. For example, it is contemplated that the instructor could demonstrate how to apply lubricating gel to the catheter 22, clean the catheter 22, record drainage, etc. It should be appreciated that the instructor could use a model to demonstrate how to insert the catheter 22, drain the bladder and remove the catheter 22.

It should be appreciated that the system 10 may contain sufficient apparatus for one or more catheter insertions; for example, apparatus for two, three, four or more months of catheter usage are contemplated. Further, it should be appreciated that refills for system 10 may be provided. In a preferred embodiment, a reorder form may be provided in system 10.

While the present invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but on the contrary is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the claims. It is thus to be understood that modifications and variations in the present invention may be made without departing from the novel aspects of this invention as defined in the claims, and that this application is to be limited only by the scope of the claims.